Corporate Medical Policy

Non-Contact Ultrasound Treatment for Wounds

File Name: non_contact_ultrasound_treatment_for_wounds
Origination: 03/2009
Last Review: 11/2024

Description of Procedure or Service

Ultrasound (US) produces vibrations of the same physical nature as sound but with frequencies above the range of human hearing (>20 KHz). US in the megahertz (MHz) range (1-3 MHz) has been used for the treatment of musculoskeletal disorders, primarily by physical therapists. Although the exact mechanism underlying its clinical effects is not known, therapeutic US has been shown to have a variety of effects at a cellular level including angiogenesis, leukocyte adhesion, growth factor and collagen production, and increases in macrophage responsiveness, fibrinolysis and nitric oxide levels. The therapeutic effects of US energy in the kilohertz (low frequency) range have been examined. It has been proposed that US in this range may improve wound healing via the production, vibration, and movement of micron-sized bubbles in the coupling medium and tissue.

The mechanical energy is typically transmitted to tissue through a coupling gel. Several high-intensity US devices with contact probes are currently available for wound debridement. Low-intensity US devices have been developed that do not require use of a coupling gel or other direct contact. The MIST Therapy System delivers US energy(40 KHz) to the wound through saline mist particles; it includes a generator, a transducer, and a disposable applicator for discharge of prepackaged saline. A second device, the Qoustic Wound Therapy System™, also uses sterile saline to deliver ultrasound energy (35 KHz) for wound debridement and irrigation.

US is intended as an adjunct to standard wound care. Therefore, the evidence is needed that demonstrates US plus standard wound care provides superior wound closure outcomes compared with standard wound care alone.

The primary end points of interest for trials of wound closure are as follows, consistent with guidance from the U.S. Food and Drug Administration for industry in developing products for treatment of chronic cutaneous ulcer and burn wounds:

1. Incidence of complete wound closure.
2. Time to complete wound closure (reflecting accelerated wound closure).
3. Incidence of complete wound closure following surgical wound closure.
4. Pain control.

Regulatory Status
In 2005, the Celleration MIST Therapy® device received marketing clearance (K050129) through the United States Food and Drug Administration's (FDA) 510(k) process, "to promote wound healing through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue exudates and bacteria." In February 2015, Celleration was acquired by Alliqua Biomedical (Langhorne, PA). In August 2020, Sanuwave acquired related UltraMIST System assets.

In 2007, the AR1000 Ultrasonic Wound Therapy System (Arobella Medical, Minnetonka, MN) received marketing clearance, listing the Celleration MIST Therapy® system and several other ultrasonic wound debridement and hydrosurgery systems as predicate devices. The AR1000 system probe uses "contact or noncontact techniques to achieve intended wound therapy modalities to promote

wound healing." Indications in the 510(k) summary are listed as "Selective and non-selective dissection and fragmentation of soft and/or hard tissue" and "Surgical, excisional or sharp-edge wound debridement (acute and chronic wounds, burns) for the removal of nonviable tissue including but not limited to diseased tissue, necrotic tissue, slough and eschar, fibrin, tissue exudates, bacteria and other matter." This device is now known as the Qoustic Wound Therapy System™. Several other devices have been approved as being substantially equivalent to the earlier devices.

Related Policies
Electrostimulation and Electromagnetic Therapy for Wounds
Topical Negative Pressure Therapy for Wounds

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

The use of non-contact ultrasound is considered investigational for the treatment of wounds. BCBSNC does not cover investigational services.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Non-Contact Ultrasound Treatment for Wounds is covered

Not applicable.

When Non-Contact Ultrasound Treatment for Wounds is not covered

Non-contact ultrasound treatment for wounds is considered investigational.

Policy Guidelines

Low-frequency ultrasound in the kilohertz range may improve wound healing. Several noncontact low frequency ultrasound (NLFU) devices have received regulatory approval for wound treatment.

For individuals who have any wound type (acute or nonhealing) who receive noncontact ultrasound therapy plus standard wound care, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. The single double-blinded, sham-controlled RCT, which included patients with nonhealing diabetic foot ulcers, had substantial methodologic flaws that limit the validity of the findings (e.g., high dropout rate, baseline differences between groups). In the remaining studies comprising the evidence base, all but one RCT comparing NLFU to standard wound care had improved (statistically significant) results on the primary outcome with NLFU. However, these studies also had several methodologic limitations. In terms of outcome assessment, complete healing is generally considered the most clinically relevant outcome. None of the RCTs evaluating venous leg ulcers reported complete healing as the primary outcome measure, and none had blinded outcome assessment. Only one RCT, which addressed split-thickness graft donor sites, reported on the proportion of patients with complete healing and had blinded outcome assessment. Another limitation of the body of evidence is that some standard of care interventions involved fewer visits than the NLFU intervention, and the differences in intensity of care resulting from this differential in face-to-face

contact could partially explain the difference in findings between intervention and control groups. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 97610

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.79, 12/13/07.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.79, 10/7/08.

Ennis WJ, Foremann P, Mozen N et al. Ultrasound therapy for recalcitrant diabetic foot ulcers: results of a randomized, double-blind, controlled, multicenter study. Ostomy Wound Manage 2005; 51(8):24-39.

Kavros SJ, Miller JL, Hanna SW. Treatment of ischemic wounds with noncontact, low-frequency ultrasound: the Mayo clinic experience, 2004-2006. Adv Skin Wound Care 2007; 20(4):221-6.

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Specialty Matched Consultant Advisory Panel – 12/2012

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Association for the Advancement of Wound Care (AAWC). Venous Ulcer Guideline. Available online at: www.guideline.gov. Last accessed February, 2014.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.79, 11/14/2013

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BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.79, 1/14/16

Specialty Matched Consultant Advisory Panel – 11/2016

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Specialty Matched Consultant Advisory Panel – 11/2021

Specialty Matched Consultant Advisory Panel – 11/2022

Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Center forDevices and Radiological Health. Guidance for Industry: Chronic Cutaneous Ulcer and Burn Wounds –Developing Products for Treatment. Rockville, MD: Food and Drug Administration; 2006 June

Food and Drug Administration. MIST[TM] Therapy System: 510(k) Premarket Notification: K050129.https://www.accessdata.fda.gov/cdrh_docs/pdf5/K050129.pdf.

Food and Drug Administration. 510(k) Summary: 510(k) -AR1000 Series K131096, Arobella Medical,LLC. 2014; https://www.accessdata.fda.gov/cdrh_docs/pdf13/K131096.pdf.

Specialty Matched Consultant Advisory Panel - 11/2023

Medical Director Review- 11/2023

Specialty Matched Consultant Advisory Panel 11/2024

Medical Director Review 11/2024

Policy Implementation/Update Information

3/16/09	Original policy issued.
6/22/10	Policy Number(s) removed (amw)
12/21/10	Specialty Matched Consultant Advisory Panel review 11/29/10. Policy accepted as written. The use of non-contact ultrasound is considered investigational for the treatment of wounds. (adn)
12/20/11	Description section and Policy Guidelines section updated. No change in policy statement, the use of non-contact ultrasound is considered investigational for wound treatment. Specialty Matched Consultant Advisory Panel review 11/30/11. (adn)
1/1/13	Reference added. Specialty Matched Consultant Advisory Panel review 12/4/12. No change to policy statement. (sk)
12/31/13	Specialty Matched Consultant Advisory Panel review 11/20/2013. No change to Policy statement. Coding update. Code 0183T deleted and code 97610 added effective 01/01/14. (sk)
2/25/14	References added. No change to Policy statement. (sk)

2/10/15	Specialty Matched Consultant Advisory Panel review 11/24/2014. Reference added. No change to Policy statement. (sk)
12/30/15	Specialty Matched Consultant Advisory Panel review 11/18/2015. (sk)
4/1/16	Reference added. Policy Guidelines updated. (sk)
1/27/17	Specialty Matched Consultant Advisory Panel review 11/30/2016. (sk)
3/31/17	Reference added. Wound Closure Endpoints information added to Description section. (sk)
12/15/17	Specialty Matched Consultant Advisory Panel review 11/29/2017. (sk)
3/9/18	Reference added. (sk)
12/14/18	Specialty Matched Consultant Advisory Panel review 11/28/2018. (sk)
2/12/19	Reference added. (sk)
12/10/19	Specialty Matched Consultant Advisory Panel review 11/20/2019. (sk)
7/21/20	Reference added. (sk)
12/8/20	Specialty Matched Consultant Advisory Panel review 11/18/2020. (sk)
10/1/21	Reference added. (sk)
11/30/21	Specialty Matched Consultant Advisory Panel review 11/17/2021. (sk)
6/30/22	Routine policy review. (sk)
5/2/23	Specialty Matched Consultant Advisory Panel review 11/16/2022. (sk)
12/5/23	References added. Specialty Matched Consultant Advisory Panel review 11/2023. Medical Director review 11/2023. (rp)
12/31/24	References added. Update regulatory section to indicate Sanuwave acquired related UltraMIST System assets. Specialty Matched Consultant Advisory Panel review 11/2024. Medical Director review 11/2024. (rp)